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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/414,384	10/07/1999	ANDREW CLARK	0037.00	3236

21968 7590 06/12/2003

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3761	35

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/414,384	CLARK ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/19/2003 (RCE)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/19/2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howlett (EP 0 808 635 A2).

As to claim 21, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphram having a particular flexibility in combination with dimensions

of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance.

As to claims 22-25, Howlett, as discussed above with respect to the particular quantity of flow resistance the particular quantity of flow rate can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

As to claims 26 and 27, the particular period of time during which the flow resistance is applied by the device of Howlett will vary with the manner of use of the device. That is, the duration of time during which flow resistance is applied is directly proportional to the duration of a particular patient's inhalation period. Consequently, this time period can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period.

As to claims 28 and 29, Howlett discloses a device (figs.2-4) for controlling delivery of an aerosolized active agent (12) to the lungs of a human patient, said device comprising a flow resistance modulator that provides a high flow resistance and subsequently provides a lower flow resistance.

While Howlett is silent as to a particular quantity of flow resistance being provided, Howlett (col.3, lines 43-50) discloses that the particular flow resistance provided by the device can be controlled by selection of a diaphram having a particular flexibility in combination with dimensions

of air inlet (31) and gap (36). Consequently, the particular quantity of flow resistance can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance. As to the claimed flow rate, the particular quantity of flow resistance and therefore the particular quantity of flow rate can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular quantity of flow resistance and/or flow rate.

Claims 30 and 31 are substantially equivalent in scope to claims 22 and 26 respectively, and are included in Howlett for the reasons discussed above with respect to claims 22 and 26.

4. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mecikalski et al.('497) in view of Schultz et al.(WO 97/40819).

As to claim 32, Mecikalski et al.(e.g. fig.3) disclose a device for controlling delivery of an aerosolized active agent (63) to the lungs of a human patient.

The difference between Mecikalski et al. and claim 32 is a flow resistance modulator that is adapted to provide a first flow resistance at the onset of the patient's inhalation and subsequently provides a second flow resistance, the second flow resistance being less than the first flow resistance.

Schultz et al., in a method for controlling delivery of an aerosolized active agent to the lungs of a patient, teach a flow resistance modulator that is adapted to provide a first flow resistance at the onset of the patient's inhalation and subsequently provides a second flow resistance, the second flow resistance being less than the first flow resistance (see abstract and page 5, lines

14-24) for the purpose of encouraging a patient to inhale at a rate which result in proper distribution of medicament within a patient's respiratory system and to provide an inhaler with means which will make the inhaler flow rate resistant.

Inasmuch as Mecikalski et al. disclose a flow rate independent inhaler but do not expressly disclose the mechanism for achieving flow rate independence, it would have been obvious to modify the inhaler of Mecikalski et al. to include means for making it flow rate independent including the use of a flow resistance modulator because it would have encouraged a patient to inhale at a rate which result in proper distribution of medicament within a patient's respiratory system and it would have provided an inhaler with means which will make the inhaler flow rate resistant as taught by Schultz et al..

As to claim 36, Schultz et al. (See abstract) disclose the first flow resistance provides a first flow rate and wherein the second flow resistance provides a second flow rate.

As to claims 33-35, Schultz et al. expressly disclose flow rates between 15 and 60 liters per minute which are within the claimed ranges. The time duration of the first flow rate in Mecikalski et al. as modified by Schultz et al. is variable in dependence upon the strength of a given patient's inhalation. That is, Schultz et al. disclose that a flow rate resistance of about .21 cm (HOH)1/2 is provided when a patient inhales at a flow rate of about 60 liters per minute. If a patient continues to inhale at that rate for 10 seconds, the higher flow rate resistance will be applied throughout the 10 seconds.

Response to Arguments

5. Applicant's arguments with respect to claims 32-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant inhalers.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

June 7, 2003

Aaron J. Lewis
Primary Examiner